.....

(Original Signature of Member)

109TH CONGRESS
1ST SESSION

# H. R. _____

To amend the Public Health Service Act to expand the scope of information required for the data bank on clinical trials of drugs, and for other purposes.

---

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

---

# A BILL

To amend the Public Health Service Act to expand the scope of information required for the data bank on clinical trials of drugs, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Fair Access to Clinical Trials Act''.

**SEC. 2. CLINICAL TRIALS DATA BANK.**

(a) IN GENERAL.—Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) in section 402, by striking subsection (j); and

(2) by inserting after section 402 the following section:

**"SEC. 402A. CLINICAL TRIALS DATA BANK.**

"(a) IN GENERAL.—

"(1) DATA BANK.—The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials (including premarket and postmarket trials) for drugs, biological products, and devices. The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

"(2) CONSULTATION.—The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

''(b) COLLECTION AND DISSEMINATION OF INFORMATION.—

''(1) COLLECTION.—In carrying out subsection (a), the Secretary shall collect, catalog, store, and disseminate the information described in such subsection.

''(2) INCLUSION OF SUBMITTED INFORMATION.—All information on clinical trials required in this section to be submitted to the Secretary shall be included in the data bank as soon as practicable after the Secretary receives the information, subject to the provisions of this section.

''(3) DISSEMINATION.—The Secretary shall disseminate information in the data bank through information systems, which shall include toll-free telephone communications available to members of the public, to health care providers, and to researchers.

''(c) TRIALS SUBJECT TO REQUIREMENTS.—

''(1) TRIALS OF SAFETY AND EFFECTIVENESS.—All clinical trials, whether federally funded or privately funded, conducted to test the safety or effectiveness (including comparative effectiveness) of a drug, biological product, or device (whether clinical trials of approved products or unapproved products)

are subject to the requirements of this section, except as provided in paragraph (2).

''(2) EXCEPTIONS.—The requirements of paragraph (1) do not apply to any of the following:

''(A) A clinical trial to determine the safety of a use of a drug if the trial is designed solely to detect major toxicities in the drug or to investigate pharmacokinetics, except that the requirements of such paragraph do apply if the trial is designed solely to investigate pharmacokinetics in a special population or populations.

''(B) A small clinical trial to determine the feasibility of a device, or a trial to test prototype devices where the primary focus is feasibility.

''(3) CERTAIN TRIALS.—The data bank may include information on a clinical trial described in subparagraph (A) or (B) of paragraph (2) with the consent of the responsible person for the trial.

''(4) RULE OF CONSTRUCTION.—This section may not be construed as applying to any classified information (as defined in subsection (l)).

''(d) REQUIRED INFORMATION.—

''(1) REGISTRATION OF TRIAL.—

"(A) IN GENERAL.—Before commencing a clinical trial that is subject to subsection (c)(1), the responsible person for the trial shall register the trial with the Secretary. Such a registration shall be in such form and be submitted in such manner as the Secretary requires, and shall include the following information:

"(i) The medical condition being studied.

"(ii) A scientific title for the trial that includes the name of the intervention, the condition, and the outcome being studied.

"(iii) A statement of whether the trial has undergone research ethics review. The statement shall provide the date on which approval was obtained pursuant to such review, or shall provide that such review is pending. In the case of a pending review, when approval is obtained, the responsible person shall provide an update that provides the date of the approval.

"(iv) The anticipated start date for the trial.

''(v) The purpose of the trial, including a statement of the interventions and comparisons involved.

''(vi) The eligibility criteria for participation in the clinical trial.

''(vii) The funding source or sources of the trial.

''(viii) A statement that—

''(I) identifies the product as an unapproved product or as an approved product, as applicable; and

''(II) in the case of an approved product, identifies the trial as investigating the approved use of the product or an unapproved use of the product, as applicable.

''(ix) The estimated completion date for the trial. For purposes of this section, the term 'completion date' means the date of the final collection of data from subjects in the trial for the outcomes described in clause (vi).

''(x) A description of the primary and secondary outcomes to be examined in the trial, the time at which the primary and

secondary outcomes will be assessed, and the dates and details of any revisions to such outcomes.

''(xi) A statement of the hypothesis being tested in the trial.

''(xii) The total number of subjects anticipated to participate in the trial.

''(xiii) Contact information for the person to whom scientific inquiries regarding the trial should be made.

''(xiv) Information on—

''(I) study design;

''(II) methods;

''(III) study phase; and

''(IV) study type.

''(xv) If the trial will test the effectiveness of the use of a product with respect to a serious or life-threatening disease or condition, the additional information described in subparagraph (B)(i).

''(xvi) With respect to an individual who is not an employee of the responsible person for the trial or of the manufacturer of the product involved, information on any agreement that the responsible person or

manufacturer has entered into with such individual that restricts in any manner the ability of the individual to—

"(I) discuss the results of the trial at a scientific meeting or any other public or private forum; or

"(II) publish the results of the trial, or a description or discussion of the results of the trial, in a scientific or academic journal.

"(xvii) After the initial submission of the registration, periodic updates to reflect changes to information provided under this subparagraph. Such updates—

"(I) shall be provided not less frequently than once every six months until information on the results of the trial is submitted under paragraph (2)(A) or a waiver is provided under paragraph (2)(D); and

"(II) shall identify the dates on which the changes were made.

"(B) SERIOUS OR LIFE-THREATENING DISEASES.—

''(i) IN GENERAL.—For a clinical trial that will test the effectiveness of the use of a product with respect to a serious or life-threatening disease or condition, the additional information referred to in subparagraph (A)(xv) is the following:

''(I) A brief summary of the trial, provided in lay language.

''(II) A description of the location of trial sites and the start date of the trial.

''(III) A point of contact for individuals desiring to enroll as subjects in the trial, including a single point of contact for all trial sites.

''(IV) The status of the trial with respect to the enrollment of subjects, stated for the trial in general and for individual trial sites.

''(V) Information that may be available—

''(aa) under a treatment investigational new drug application, or a treatment investigational device exemption, that has been submitted to the Secretary under section 561(c) of

the Federal Food, Drug, and Cosmetic Act (relating to expanded access protocols); or

''(bb) as a Group C cancer drug (as defined by the National Cancer Institute).

''(ii) FORMATTING FOR GENERAL PUBLIC.—The information provided under clause (i) shall be in a format that can be readily accessed and understood by members of the general public, including patients seeking to enroll as subjects in clinical trials.

''(C) LABELS OF APPROVED PRODUCTS.—If a clinical trial registered under subparagraph (A) is investigating an approved product and the label for such product is included on the Internet site of the Food and Drug Administration, the information in the data bank concerning the trial shall include an electronic link to such label for individuals accessing the data bank through the Internet.

''(D) UNIQUE IDENTIFIER.—The Secretary shall assign to each clinical trial registered under subparagraph (A) a unique identifier for purposes of the data bank. The Secretary shall seek to ensure

that such identifiers comply with international standards for identifying clinical trials.

''(E) MODIFICATIONS REGARDING REQUIRED INFORMATION.—Notwithstanding clauses (i) through (xvi) of subparagraph (A), requirements under such clauses may be modified by the Secretary, and additional requirements for the provision of information in registrations under such subparagraph may be established by the Secretary, in order to ensure the nonmisleading disclosure of important information from clinical trials.

''(2) SUBMISSION OF RESULTS OF TRIAL.—

''(A) IN GENERAL.—The responsible person for a clinical trial that is subject to subsection (c)(1) shall provide to the Secretary information described in subparagraph (B) on the results of the trial, subject to subparagraph (D). The information shall be provided in the form of a structured abstract and in such manner as the Secretary may require, in a form not likely to mislead or distort the results.

''(B) INFORMATION.—For purposes of subparagraph (A), the information described in this subparagraph on the results of a clinical trial is the following:

''(i) The actual completion date of the trial and the reasons for any difference from such actual date and the estimated completion date submitted pursuant to paragraph (1)(A)(ix), or, if the trial is terminated prior to completion, the termination date and reasons for such termination.

''(ii) Primary and secondary outcomes, presented succinctly as quantitative data and as tests of hypotheses.

''(iii) Information on the number and type of significant adverse events in subjects that may be associated with the product involved, including such events for which a causal relationship has not been established.

''(iv) A citation to each covered article published in a peer-reviewed scientific or academic journal. An article published in such a journal is a covered article for purposes of this clause if—

''(I) the article discusses the results of the trial;

''(II) the responsible person or the principal investigator for the clinical trial contributed to the article; and

''(III) MEDLINE includes a citation to the article.

''(v) A description of the process used to review the results of the trial, including a statement about whether the results have been peer reviewed by reviewers independent of the sponsor.

''(vi) If the trial is investigating an unapproved product or an unapproved use of an approved product, a statement, as appropriate, displayed prominently at the beginning of information in the data bank concerning the trial, that the Food and Drug Administration—

''(I) is currently reviewing an application for approval of such product or use to determine whether the use is safe and effective;

''(II) has disapproved an application for approval of such product or use;

"(III) has reviewed an application for approval of such product or use but the application was withdrawn prior to approval or disapproval; or

"(IV) has not reviewed or approved such product or use as safe and effective.

"(vii) If data from the trial has not been submitted to the Food and Drug Administration, an explanation of why it has not been submitted.

"(viii) A statement providing such information on the protocol for the trial as may be necessary to evaluate the results of the trial. Criteria issued by the Secretary under subsection (k) shall include criteria regarding information that is required for purposes of such statements.

"(ix) In the group of subjects receiving the product, and in each comparison group of subjects, the percentage of individuals who ceased participation as subjects and the reasons for ceasing participation.

"(x) Basic demographic information on subjects.

"(xi) With respect to an individual who is not an employee of the responsible person for the trial or of the manufacturer of the product involved, information (to the extent not submitted under paragraph (1)(A)(xvi) on any agreement that the responsible person or manufacturer has entered into with such individual that restricts in any manner the ability of the individual to—

"(I) discuss the results of the trial at a scientific meeting or any other public or private forum; or

"(II) publish the results of the trial, or a description or discussion of the results of the trial, in a scientific or academic journal.

"(xii) After the initial submission of information on the results, periodic updates to reflect changes in the information submitted pursuant to this subparagraph. Such updates—

''(I) shall be provided not less frequently than once every six months during the 10-year period beginning on the date on which information on the results is due under subparagraph (C)(i); and

''(II) shall identify the dates on which the changes were made.

''(C) DUE DATE FOR RESULTS.—

''(i) IN GENERAL.—Information required under subparagraph (A) on the results of a clinical trial shall be submitted to the Secretary—

''(I) not later than one year after the earlier of—

''(aa) the estimated completion date of the trial, as submitted under paragraph (1)(A)(ix); or

''(bb) the actual completion date of the trial, or the actual date of the termination of the trial before completion, as applicable; or

"(II) by such later date as may apply under an extension under clause (iii).

"(ii) REPORTS REGARDING DUE DATE IN EXCESS OF THREE YEARS.—If the due date under clause (i) for information on the results of a clinical trial is a date that is more than three years after the date on which the trial was registered under paragraph (1)(A), the following applies:

"(I) Upon the expiration of such three-year period, the responsible person for the trial shall submit to the Secretary a report that describes the progress being made toward submission of the results.

"(II) For each one-year period that lapses after the submission of the report under subclause (I), the responsible person shall submit to the Secretary an additional report that describes such progress, except that no report is required under this subclause after such due date.

"(iii) EXTENSIONS.—

"(I) IN GENERAL.—The Secretary may provide an extension of the due date under clause (i)(I) for information on the results of a clinical trial if the responsible person for the trial submits to the Secretary a written request that demonstrates good cause for the extension and provides an estimate of the date on which information on the results will be submitted. More than one such extension may be provided by the Secretary for the clinical trial involved.

"(II) EXTENSIONS REGARDING JOURNAL PUBLICATION.—

"(aa) ARTICLE UNDER CONSIDERATION FOR PUBLICATION.—With respect to the submission of information on the results of a clinical trial, the Secretary shall under subclause (I) provide an extension of 18 months after the due date under clause (i)(I) (or if such an extension previously has been pro-

vided, 18 months beginning upon the expiration of the most recent extension) if—

"(AA) the request under such subclause demonstrates that an article providing the information described in subparagraph (B) has been submitted to a peer-reviewed scientific or academic journal for which references are included in MEDLINE, and the request demonstrates that the article is being considered by the journal for publication; and

"(BB) such request is made before the expiration of the one-year period described in clause (i)(I) (or if such an extension previously has been provided, before the expiration of the most recent extension).

"(bb) ARTICLE ACCEPTED FOR PUBLICATION.—If the responsible person for a clinical trial has received an extension under item (aa) regarding the trial, the Secretary shall provide an additional extension of six months, beginning upon the expiration of such first extension, if the person demonstrates to the Secretary, before the expiration of the first extension, that the article involved has been accepted for publication by a journal referred to in such item.

"(cc) PUBLICATION DURING PERIOD OF EXTENSION.—With respect to an extension under item (aa) or (bb), if during the period of extension the article involved is published in a journal referred to in item (aa)—

"(AA) the extension terminates upon publication of the article; and

"(BB) the due date under clause (i) regarding the clinical trial involved becomes the date of such publication.

"(D) WAIVERS REGARDING RESULTS OF TRIAL.—With respect to the requirement under subparagraph (A) to submit to the Secretary information on the results of a clinical trial, the Secretary may waive the requirement upon a written request to the Secretary by the responsible person for the trial if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest or consistent with the protection of the public health. The Secretary shall ensure that information on each such waiver is included in the data bank.

"(3) UPDATES; TRACKING OF CHANGES IN SUBMITTED INFORMATION.—The Secretary shall ensure that updates submitted to the Secretary under paragraphs (1)(A)(xvii) and (2)(B)(xii) do not result in the removal from the data bank of the original submissions or of any preceding updates, and that information in the data bank is presented in a manner

that enables users to readily access each original submission and to track the changes made by the updates.

''(e) ENFORCEMENT.—

''(1) EFFECT OF FAILURE TO PROVIDE INFORMATION.—In the case of a clinical trial that is subject to subsection (c)(1):

''(A) Subject to paragraph (2), if the Secretary determines that with respect to the trial the responsible person is not in compliance with requirements under subsection (d) to submit information to the Secretary, the following applies:

''(i) Such person is subject to a civil penalty in accordance with paragraph (3).

''(ii) The person is, during the period of such noncompliance, ineligible for any award from the Secretary of a grant, cooperative agreement, or contract for the conduct of any trial that is subject to subsection (c)(1), including all current awards for such trials, except that such period of ineligibility may not exceed five years.

''(iii) The person is subject to the sanction described in paragraph (4) (relat-

ing to the investigational use of products) if the noncompliance is serious or repeated.

"(B) The submission to the Secretary of information under subsection (d) that is false or misleading constitutes noncompliance for purposes of subparagraph (A).

"(2) PROCEDURES REGARDING NONCOMPLIANCE.—

"(A) NOTICE OF NONCOMPLIANCE.—With respect to a clinical trial that is subject to subsection (c)(1), if the Secretary determines that the responsible person involved has not submitted information to the Secretary in accordance with subsection (d), the Secretary—

"(i) shall transmit to such person a notice specifying the required information and stating that the person will be subject to applicable sanctions referred to in paragraph (1)(A) if the information is not submitted to the Secretary within 90 days after the date on which the notice is transmitted;

"(ii) shall through the notice inform the person that under subsection (h) the

person is being identified in the data bank as a noncompliant person; and

"(iii) shall through the notice inform the person of the provisions of paragraph (8).

"(B) FAILURE TO CORRECT NONCOMPLIANCE.—Upon the expiration of the 90-day period beginning on the date on which the Secretary transmits a notice under subparagraph (A) to a responsible person, the Secretary shall impose on such person the sanctions referred to in clauses (i) and (ii) of paragraph (1)(A) if the information involved has not been submitted to the Secretary, except that the Secretary may elect not to impose such a sanction or sanctions if the Secretary determines that the noncompliance involved is not serious or repeated.

"(3) AMOUNT OF CIVIL PENALTY; HEARING PROCEDURES.—With respect to a civil penalty imposed under paragraph (1)(A)(i) on a responsible person:

"(A) The amount of the penalty shall be not more than a total of $15,000 for all violations adjudicated in a single proceeding in the case of an individual, and not more than

$10,000 per day until the violation is corrected in the case of any other person, except that if the person is a nonprofit entity the penalty may not exceed a total of $15,000 for all violations adjudicated in a single proceeding.

''(B) The provisions of paragraphs (3) through (5) of section 303(f) of the Federal Food, Drug, and Cosmetic Act apply to the imposition of such a penalty to the same extent and in the same manner as such provisions apply to a penalty imposed under such section 303(f).

''(4) ELIGIBILITY FOR INVESTIGATIONAL USE EXEMPTIONS.—In any case in which the noncompliance referred to in paragraph (1)(A) is serious or repeated, the Secretary may, upon the expiration of the 90-day period beginning on the date on which the Secretary transmits a notice under paragraph (2)(A) to the responsible person involved, consider such person to be ineligible for any future exemptions under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act for any investigation until the violation is corrected, except that such period of ineligibility may not exceed five years. The Secretary may impose such sanction only after no-

tice and an opportunity for a hearing, unless a hearing regarding such noncompliance is held pursuant to paragraph (3) and through such hearing the Secretary determines that the noncompliance was serious or repeated.

''(5) FAILURE TO SUBMIT INFORMATION ON RESULTS; REQUIREMENT OF REPORTS.—In any case in which the noncompliance referred to in paragraph (1)(A) is a failure to submit to the Secretary information on the results of the trial by the due date under subsection (d)(2)(C)(i), the Secretary shall order the responsible person to submit to the Secretary periodic reports on the progress being made toward submission of information on the results, which reports shall be submitted not less frequently that once each year until the information is submitted to the Secretary.

''(6) RULE OF CONSTRUCTION.—With respect to a responsible person who is subject to a sanction referred to in paragraph (1)(A), this subsection may not be construed as providing that any other person associated with the clinical trial involved is subject to the sanction.

''(7) USE OF FUNDS.—

''(A) IN GENERAL.—The Secretary shall deposit the funds collected under paragraph (1)(A) into an account and use such funds, in consultation with the Director of the Agency for Healthcare Research and Quality, to fund studies that compare the clinical effectiveness of two or more treatments for a disease or condition.

''(B) FUNDING DECISIONS.—The Secretary shall award funding under subparagraph (A) based on a priority list established not later than six months after the date of enactment of the Fair Access to Clinical Trials Act by the Director of the Agency for Healthcare Research and Quality and periodically updated as determined appropriate by the Director.

''(8) DISCLOSURE OF CERTAIN INFORMATION.—In the case of a responsible person to whom a notice under paragraph (2) has been transmitted, if such person has not submitted the information involved to the Secretary by the expiration of the 180-day period beginning on the date on which the notice was transmitted to the person, the following applies:

''(A) Notwithstanding section 301(j) of the Federal Food, Drug, and Cosmetic Act, section 1905 of title 18, United States Code, subsection

(j)(4)(C)(ii) of this section, or any other provision of law, the Secretary shall begin disclosure through the data bank of the definitions of the primary and secondary outcomes for the clinical trial involved unless the definitions have already been disclosed pursuant to subsection (j)(4)(C)(ii).

''(B) Notwithstanding section 301(j) of the Federal Food, Drug, and Cosmetic Act, section 1905 of title 18, United States Code, or any other provision of law, if the responsible person is the manufacturer or a distributor of the product involved, the Secretary shall through the data bank disclose information on the product that—

''(i) is required to be submitted under subsection (d); and

''(ii) is included in any FDA application for the product (as defined in subsection (l)) that the responsible person has submitted to the Secretary.

''(f) TRIALS CONDUCTED OUTSIDE UNITED STATES.—

''(1) IN GENERAL.—If a covered person submits to the Secretary an FDA application for a product

(as defined in subsection (l)), and one or more of the investigations presented to the Secretary by such person for purposes of the document are covered foreign investigations, the person is subject to a civil penalty—

"(A) in any case in which information on the investigation has not, as of the date on which the application is submitted to the Secretary, been submitted to the data bank to the same extent as would have been required as of such date under subsection (d) if the investigation had been subject to subsection (c)(1); and

"(B) in any case in which, after such date, information on the investigation is not submitted to the data bank to the same extent as would be required if the investigation were subject to subsection (c)(1).

"(2) PROCEDURES.—The provisions of paragraphs (2), (3), (6), and (7) of subsection (e) apply to a civil penalty under paragraph (1) to the same extent and in the same manner as such provisions apply to a civil penalty under subsection (e)(1)(A).

"(3) DEFINITIONS.—With respect to an FDA application for a product, for purposes of this subsection:

"(A) The term 'covered foreign investigation' means an investigation that was not conducted in any of the States and was not subject to subsection (c)(1).

"(B) The term 'covered person' means the person who was the principal investigator or the responsible person for any of the covered foreign investigation or investigations involved.

"(g) LABELING AND ADVERTISEMENTS.—-

"(1) IN GENERAL.—If a person disseminates labeling, or an advertisement or other descriptive printed matter, for an approved product for human use and the labeling, advertisement, or other matter refers to an investigation that is not subject to subsection (c)(1), and if the person was the principal investigator or the responsible person for the investigation, the person is subject to a civil penalty—

"(A) in any case in which information on the investigation has not, as of the date on which the labeling, advertisement, or other matter enters the market, been submitted to the data bank to the same extent as would have been required as of such date under subsection (d) if the investigation had been subject to subsection (c)(1); and

"(B) in any case in which, after such date, information on the investigation is not submitted to the data bank to the same extent as would be required if the investigation were subject to subsection (e)(1).

"(2) PROCEDURES.—The provisions of paragraphs (2), (3), (6), and (7) of subsection (e) apply to a civil penalty under paragraph (1) to the same extent and in the same manner as such provisions apply to a civil penalty under subsection (e)(1)(A).

"(h) PUBLIC LIST OF NONCOMPLIANT RESPONSIBLE PERSONS.—In any case in which a notice of noncompliance is submitted to a person under subsection (e)(2)(A), (f)(2), or (g)(2), the Secretary shall include with the information in the data bank that concerns the clinical trial involved a statement, prominently displayed, that such person has not reported information to the data bank as required by law, which statement shall remain in the data bank until the information involved is submitted to the Secretary. For purposes of the preceding sentence, the Secretary shall maintain a list of noncompliant persons that is available to the public.

"(i) COMPLIANCE AUDITS.—

"(1) IN GENERAL.—The Secretary shall conduct periodic audits of responsible persons for clin-

ical trials that are subject to subsection (c)(1) in order to determine whether such persons have submitted information as required in subsection (d), including determining whether any of the information is false or misleading.

''(2) PRIORITY.—In conducting audits under subparagraph (A), the Secretary shall give priority to responsible persons for clinical trials who have at any time been included on the list under subsection (h), taking into account the number and severity of the violations involved.

''(j) GENERAL PROVISIONS.—

''(1) AUTHORITY OF SECRETARY.—

''(A) INCLUSION OF STATEMENTS TO AVOID MISINTERPRETATIONS.—The Secretary may include in the data bank such statements as the Secretary determines to be appropriate to assist the public in avoiding misinterpretations of information in the data bank. Statements under the preceding sentence may include statements regarding the data bank in general and statements regarding particular items of information submitted to the data bank. The Secretary may not under the pre-

ceding sentence alter any information as submitted.

"(B) FALSE OR MISLEADING INFORMATION.—If the Secretary determines that information presented or cited in the data bank is false or misleading, the Secretary shall, promptly after making such determination, identify in the data bank the information as false or misleading (as applicable), and shall, to the extent practicable, include in the data bank an accurate version of the information. The Secretary shall in addition make appropriate public notification.

"(2) LIMITATION ON DISCLOSURES.—This section may not be construed as authorizing the disclosure of information through the data bank if—

"(A) such disclosure would constitute a clearly unwarranted invasion of personal privacy; or

"(B) such information concerns a method or process which as a trade secret is entitled to protection within the meaning of section 301(j) of the Federal Food, Drug, and Cosmetic Act.

"(3) INSTITUTIONAL REVIEW BOARDS.—The Secretary shall amend part 46 of title 45, Code of

Federal Regulations, and parts 50, 56, and 812 of title 21 of Code, to provide as follows:

''(A) That the functions of institutional review boards under such parts include—

''(i) determining whether clinical trials that are subject to subsection (c)(1) are registered under subsection (d)(1)(A); and

''(ii) denying the approval of the boards for such trials that are not so registered.

''(B) That any approval of an institutional review board regarding such a trial is not effective under such parts if the trial is not so registered.

''(C) That upon request of an institutional review board for such a trial, the Secretary will provide to the board a copy of the registration for the trial under subsection (d)(1)(A) (which copy will be the registration as submitted to the Secretary, together with all updates to the registration).

''(4) DISCLOSURE OF INFORMATION.—

''(A) IN GENERAL.—The Secretary shall disseminate information in the data bank through an Internet site or sites under subpara-

graph (B) and through any other means determined appropriate by the Secretary. Information required in this section to be submitted to the Secretary shall not be considered confidential commercial information or trade secrets, notwithstanding any other provision of law.

''(B) INTERNET SITES.—

''(i) IN GENERAL.—The Secretary shall operate one or more searchable Internet sites for purposes of presenting to clinicians and researchers, and to patients seeking to enroll as subjects in clinical trials, information in the data bank. The Secretary shall ensure that—

''(I) such a site, or a portion of a site, is designed specifically for use by clinicians and researchers; and

''(II) such a site, or a portion of a site, is designed specifically for use by patients seeking to enroll as subjects in clinical trials.

''(ii) RELATION TO CERTAIN INTERNET SITE.—The Secretary shall ensure that the Internet site or portion thereof operated under clause (i)(II) includes infor-

mation of the type that was available on ClinicalTrials.gov as of the day before the date of the enactment of the Fair Access to Clinical Trials Act (relating to serious or life-threatening diseases). This section may not be construed as requiring the Secretary to terminate or alter ClinicalTrials.gov, or as prohibiting the Secretary from terminating or altering such site.

''(C) REGISTRATION INFORMATION; DATE OF DISCLOSURE.—In the case of information regarding a clinical trial that is submitted to the Secretary under subsection (d)(1), disclosures of the information through the data bank shall, subject to subsection (e)(8), begin in accordance with the following:

''(i) All such disclosures shall begin promptly after the registration involved is submitted to the Secretary, other than disclosure of the definitions of the primary and secondary outcomes.

''(ii) Disclosure of the definition of the primary and secondary outcomes shall begin at the same time as disclosure of the

results of the trial begin under subparagraph (D)(i), unless the responsible person for the trial requests earlier disclosure, or unless the Secretary requires earlier disclosure pursuant to subparagraph (E)(ii).

''(D) RESULTS OF TRIAL; DATE OF DISCLOSURE.—

''(i) IN GENERAL.—In the case of information regarding a clinical trial that is submitted to the Secretary under subsection (d)(2)(A), disclosures of the information through the data bank shall begin promptly after the information is submitted to the Secretary, subject to clause (ii).

''(ii) WAIVER REGARDING RESULTS OF TRIAL.—In the case of information on waivers that is contained in the data bank under subsection (d)(2)(D), disclosures of the information through the data bank shall begin promptly after the waiver is provided.

''(E) STUDY REGARDING DATE FOR DISCLOSURE OF PRIMARY AND SECONDARY OUTCOMES; AUTHORITY OF SECRETARY.—

"(i) IN GENERAL.—The Secretary, in consultation with appropriate government agencies, shall conduct a study to determine whether the delay in disclosure of the definitions of the primary and secondary outcomes under clause (ii) of subparagraph (C), relative to the timing of disclosures under clause (i) of such subparagraph, is consistent with the protection of the public health. Not later than three years after the date of the enactment of the Fair Access to Clinical Trials Act, the Secretary shall complete the study and submit to the appropriate committees of the Congress a report describing the findings of the study.

"(ii) AUTHORITY OF SECRETARY.—If on the basis of the study under clause (i) the Secretary determines that the delay referred to in such clause is not consistent with the protection of the public health, the Secretary shall by regulation establish an earlier date for disclosures of the definitions referred to in such clause, which date may not be earlier than the date of disclosures under subparagraph (C)(i). A final

rule shall be issued under the preceding sentence not later than one year after the date on which the report under clause (i) of this subparagraph is submitted to the appropriate committees of the Congress.

''(5) LIMITATION ON USE OF INFORMATION.—Information on a clinical trial that is disclosed through the data bank, including information disclosed under subsection (e)(8), may not be used by a person other than the responsible person for the trial (or an entity acting with the permission of such person) as part of any FDA application (as defined in subsection (l)) unless the information is available in accordance with law from a source other than the data bank.

''(6) SUBMISSION FORMAT AND TECHNICAL STANDARDS.—

''(A) IN GENERAL.—The Secretary shall, to the extent practicable, accept submissions required in subsection (d) in an electronic format and shall establish interoperable technical standards for such submissions.

''(B) CONSISTENCY OF STANDARDS.—To the extent practicable, the standards established under subparagraph (A) shall be consistent

with standards adopted by the Consolidated Health Informatics Initiative (or a successor organization to such Initiative) to the extent such Initiative (or successor) is in operation.

''(7) TRIALS NOT INVOLVING DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES.—The Secretary shall establish procedures and mechanisms to allow for the voluntary submission to the Secretary of information described in subsection (d)(2)(B) on clinical trials that are not subject to subsection (c)(1). Information received by the Secretary under this paragraph shall be included in the data bank. In any case in which it is in the interest of public health, the Secretary may require that information on such trials be submitted to the Secretary. Failure to comply with such a requirement shall be deemed to be a failure to submit information as required under this section, and the appropriate remedies and sanctions under this section shall apply.

''(8) AWARD FOR CONDUCT OF CLINICAL TRIAL; COMPLIANCE COSTS AS DIRECT COSTS.—In administering an award of a grant, contract, or cooperative agreement that is subject to subsection (c)(1), the Secretary shall consider the costs of complying

with requirements under this section as part of the direct costs of conducting the clinical trial involved.

''(k) CRITERIA.—The Secretary shall establish criteria regarding compliance with this section.

''(l) DEFINITIONS.—For purposes of this section:

''(1) The term 'approved product' means a product that is approved, licensed, or cleared for commercial distribution under section 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.

''(2) The term 'approved use', with respect to an approved product, means a use that is an approved, licensed, or cleared use of the product under a provision of law referred to in paragraph (1).

''(3) The term 'biological product' has the meaning given such term in section 351.

''(4) The term 'classified', with respect to information, means information on matters referred to in section 552(b)(1)(A) of title 5, United States Code.

''(5) The term 'clinical trial', with respect to a product, means a clinical investigation within the meaning of section 505(i) of the Federal Food, Drug, and Cosmetic Act (in the case of drug), or within the meaning of section 520(g) of such Act (in the case of a device), as applicable, except that such

term does not include such an investigation that does not prospectively assign human subjects to intervention or comparison groups to study the causal relationship between a medical intervention and an outcome.

''(6) The term 'data bank' means the data bank under subsection (a).

''(7) The term 'device' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

''(8) The term 'drug' has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act. Such term includes a biological product.

''(9) The term 'FDA application', with respect to a product, means each of the following:

''(A) An application or report submitted to the Secretary for the purpose of seeking a decision by the Secretary for the product to become an approved product (as defined in paragraph (1)). Such term includes a supplement to such an application or report.

''(B) An application for an exemption under section 505(i) or 520(g) of the Federal

Food, Drug, and Cosmetic Act (relating to investigational use).

''(10) The term 'MEDLINE' means the bibliographic electronic data base of references to journal-published articles that is operated by the National Library of Medicine and is designated by such Library as the Medical Literature, Analysis, and Retrieval System Online.

''(11) The term 'postmarket', with respect to a clinical trial to investigate a product, means a clinical trial that is conducted after the product has become an approved product.

''(12) The term 'product' means a drug, biological product, or device.

''(13) The term 'responsible person', with respect to a clinical trial that is subject to subsection (c)(1), has the following meaning, as applicable:

''(A) In any case in which an application has with respect to the trial been submitted for an exemption under section 505(i) or 520(g)(2)(A) of the Federal Food, Drug, and Cosmetic Act, such term means the entity who, within the meaning of such section, is the sponsor of the trial.

"(B) In any case in which such an application has not been submitted, such term means the entity who is or will be providing the largest share of the monetary support for the trial (without regard to any in-kind support for the trial), subject to the following:

"(i) If the Federal Government or a State is or will be providing the largest share, such term means the principal investigator for the trial.

"(ii) If a nonprofit private entity is or will be providing the largest share, such term means the principal investigator for the trial in any case in which such entity and investigator have jointly certified to the Secretary that the investigator will be the responsible person for purposes of this section.

"(iii) If two or more entities provide equal monetary support for the trial and no other entity provides a greater amount of monetary support, such term means each of the entities providing such equal support, other than the Federal Government or a State.

"(iv) Notwithstanding clauses (i) through (iii), if an entity submits to the Secretary a written request to be the responsible person for purposes of this section, such term means that entity in any case in which the Secretary determines that the entity is responsible for conducting the trial, has access to and control over the data, has the right to publish the results of the trial, and has the responsibility to meet all of the requirements under this section that are applicable to responsible persons.

"(14) The term 'unapproved product' means a product that is not an approved product.

"(15) The term 'unapproved use', with respect to an approved product, means a use that is not an approved use.

"(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for fiscal year 2005 and each subsequent fiscal year. Fees collected under section 736 or 738 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this section.".

(b) APPLICABILITY.—With respect to section 402A of the Public Health Service Act (as added by subsection (a) of this section):

(1) Subject to paragraphs (2) and (3), such section 402A applies to all clinical trials that are commenced on or after the date of the enactment of this Act, or are in progress as of such date, to the extent the trials are described in subsection (c)(1) of such section and not within an exception under subsection (c)(2) of such section.

(2) For purposes of paragraph (1), such section 402A applies to a trial that is in progress only if the final data collection from subjects in the trial on the primary outcome has not been completed as of the date of the enactment of this Act. Such a trial becomes subject to such section upon the expiration of 30 days after such date of enactment, except that registration information required pursuant to subsection (d)(1) of such section is due upon the expiration of such 30 days.

(3) The Secretary of Health and Human Services (referred to in this paragraph as the ''Secretary'') shall establish procedures and mechanisms to allow for the voluntary submission to the Secretary of information described in subsection

(d)(2)(B) of such section 402A on clinical trials that were completed prior to such date of enactment, or were in progress as of such date but not subject to paragraph (2). Information received by the Secretary under this paragraph shall be included in the data bank. In any case in which it is in the interest of public health, the Secretary may require that information on such trials be submitted to the Secretary. Failure to comply with such a requirement shall be deemed to be a failure to submit information as required under such section, and the appropriate remedies and sanctions under such section shall apply.

(4) Definitions applicable to such section 402A apply for purposes of this subsection.

(c) RULE OF CONSTRUCTION REGARDING PRIOR PROVISION.—With respect to the data bank program under section 402(j) of the Public Health Service Act as in effect on the day before the date of the enactment of this Act:

(1) Subsection (a) shall be construed as a transfer and modification of the program, and not as the termination of the program and the establishment of a different program.

(2) All information contained in the data bank on such day shall continue to be contained in the data bank, subject to section 402A of the Public Health Service Act (as added by subsection (a) of this section) or other applicable provisions of law.

(d) CONFORMING AMENDMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(1) in section 505(i), by adding at the end the following paragraph:

''(5) The provision of an exemption under paragraph (1) is subject to section 402A(e)(4) of the Public Health Service Act (relating to a data bank on clinical trials).''; and

(2) in section 520(g), by adding at the end the following paragraph:

''(8) The provision of an exemption under paragraph (2)(A) is subject to section 402A(e)(4) of the Public Health Service Act (relating to a data bank on clinical trials).''.

**SEC. 3. REPORTS.**

(a) IMPLEMENTATION REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to the appropriate com-

mittees of the Congress a report on the status of the implementation of the requirements of the amendments made by section 2 that includes a description of the number and types of clinical trials for which information has been submitted under such amendments.

(b) DATA COLLECTION.—

(1) IN GENERAL.—The Secretary shall request the Institute of Medicine to enter into a contract with the Secretary for the conduct of a study concerning the extent to which information submitted to the data bank under section 402A of the Public Health Service Act (as added by section 2(a)) has impacted the public health.

(2) REPORT.—The Secretary shall ensure that the contract under paragraph (1) provides that, not later than six months after the date on which a contract is entered into, the Institute of Medicine will submit to the Secretary a report on the results of the study under such paragraph, and that the report may include any recommendations of the Institute for changes to the program carried out under the section referred to in such paragraph that the Institute considers appropriate to benefit the public health.